

DROLEPTAN® Injection

Contains 2.5 mg/mL droperidol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Droleptan Injection. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Droleptan Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What Droleptan injection is used for

Droleptan Injection is a tranquilliser used to:

- calm patients before surgery
- reduce nausea and vomiting which may occur with anaesthesia
- help produce or maintain anaesthesia
- help reduce anxiety and pain when used with strong pain killers during surgery
- help manage severe agitation, aggression and over-activity.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is not enough information to recommend the use of this medicine for children under the age of 2 years.

Before you are given Droleptan Injection

When you must not be given it

You should not be given Droleptan Injection if you have an allergy to:

- any medicine containing droperidol
- any of the ingredients listed at the end of this leaflet
- any other similar medicines such as haloperidol.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Droleptan Injection should not be given if you have:

- severe drowsiness and slowness as a result of brain disease or damage
- Parkinson's disease
- pheochromocytoma, a type of tumour, which causes high blood pressure
- a rare heart disorder known as QT prolongation. Sometimes this runs in families.
- a slow heart beat

- low levels of salt in your blood.

Do not breast-feed if you are being given this medicine.

The active ingredient in Droleptan Injection passes into breast milk and there is a possibility that your baby may be affected.

Droleptan Injection should not be given if you are intoxicated with alcohol.

You should not be given this medicine if the solution is discoloured, cloudy, turbid, or a precipitate or particles are present.

The solution is normally a clear, colourless liquid.

The doctor or nurse will check to ensure the medicine is not past its expiry date and has not been tampered with.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease
- a family history of sudden death
- kidney disease
- lung disease
- dementia, if you are over 65 years of age
- history of blood clots or strokes
- vomiting or diarrhoea
- epilepsy or convulsions.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Droleptan Injection.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket, health food shop, naturopath or herbalist.

Some medicines and Droleptan Injection may interfere with each other. These include:

- medicines that act on the heart, such as quinidine, disopyramide, procainamide, amiodarone, sotalol and bepridil
- medicines used to treat depression, such as maprotiline and amitriptyline
- medicines used to treat mental illness, such as phenothiazines, pimozide and sertindole
- medicines used to treat allergies or hay fever, such as astemizole and terfenadine
- alcohol or medicines that make you feel drowsy or slow to react, such as sleeping tablets, tranquillisers or strong pain killers
- medicines used to treat high blood pressure
- medicines used to treat epilepsy, such as phenobarbitone, carbamazepine or phenytoin
- medicines used to treat Parkinson's disease such as levodopa, bromocriptine, lisuride
- cisapride, a medicine used to treat certain digestive problems
- halofantrine, a medicine used to treat malaria
- sparfloxacin, an antibiotic used to treat lung infections

- some medicines used to treat viral infections, fungal infections or bacterial infections such as ritonavir, itraconazole or ciprofloxacin.

These medicines may be affected by Droleptan Injection or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How Droleptan Injection is given

Droleptan Injection must only be given by a doctor or nurse.

How it is given

Droleptan Injection will be injected into a muscle or slowly into a vein.

How much is given

Your doctor will decide how much Droleptan Injection you will need. This will depend on your age, body weight, medical history and condition.

If you are given too much (overdose)

As Droleptan Injection is always given to you in a hospital under the supervision of a doctor, it is unlikely that you will receive an overdose.

Symptoms of an overdose may include:

- unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs
- uncontrollable movements
- dizziness, light-headedness
- extreme drowsiness

- shallow breathing
- fits
- irregular heart beat.

If you notice any symptoms of an overdose immediately contact your doctor or go to the Emergency Department at the nearest hospital.

Contact the Poisons Information Centre on 13 11 26 for further advice on overdose management.

While you are being given Droleptan Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Droleptan Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you become pregnant while being treated with this medicine, tell your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Droleptan Injection affects you.

This medicine may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are being given this medicine.

If you drink alcohol, dizziness or drowsiness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood

pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Droleptan Injection.

This medicine helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you are at increased risk of developing side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- tremor, shaky hands, an unsteady walk or uncontrolled arm, leg, head, neck or eye movement
- uncontrollable twitching of the tongue, face, mouth or jaw
- muscle spasm causing the head and heels to bend backward and the body to bend forwards
- drowsiness, dizziness, anxiety, agitation, restlessness or nervousness
- chills or shivering
- seeing, feeling, or hearing things that are not there
- blurred vision
- yellowing of the skin or eyes, called jaundice
- skin rashes, increased sensitivity of the skin to sunlight
- loss of hair
- changes in the menstrual cycle

- breast pain, breast enlargement, unusual secretion of breast milk or changes in sex drive in men and women
- impotence
- difficulty urinating
- loss of appetite or an uncomfortable feeling in the stomach after eating
- increased saliva, dry mouth
- nausea, vomiting, constipation or diarrhoea.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- allergic reaction with rash and swelling of the face, lips, mouth, tongue or throat which may cause difficulty breathing
- changes in the rhythm or rate of the heart beat
- difficulty breathing, wheezing and coughing
- sudden severe headache
- loss of vision
- loss of coordination
- slurred speech
- chest pain
- numbness, heat, or swelling in the arms or legs
- fever, sweating, increased body temperature, stiff muscles, confusion and reduced consciousness.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given Droleptan Injection

Storage

Droleptan Injection will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Droleptan Injection will only be opened when it is time for you to have the injection.

Product description

What it looks like

Droleptan Injection is a clear colourless liquid in an amber glass ampoule.

Ingredients

Droleptan Injection contains 2.5 mg/mL droperidol in Water for Injections.

It also contains:

- tartaric acid
- mannitol.

This medicine does not contain lactose, sucrose, gluten, tartrazine, alcohol, dyes or preservatives.

Supplier

Droleptan Injection is supplied in Australia by:

Phebra Pty Ltd
19 Orion Road, Lane Cove West,
NSW 2066, Australia.
Telephone: 1800 720 020

Droleptan Injection is distributed in New Zealand by:

AFT Pharmaceuticals Ltd
PO Box 33-203, Auckland.
Telephone: +64 9 4880232

Droleptan® Injection 1 mL ampoule:

AUST R 46841

Phebra product code - INJ080

Date of most recent amendment: 02
March 2016.

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